Ronsod Exhibit

SECOND REVISED CALCULATION OF PATENT TERM EXTENSION FOR BONIVA

Applicable Dates

a) Effective date of the investigational new drug application (IND) and IND number:

October 30, 1994 (Exhibit H)

IND 46,266

b) Date on which a New Drug Application (NDA) was initially submitted and NDA number:

July 15, 2002 (Exhibit F) NDA No. 21-455

c) Date on which NDA was approved:

May 16, 2003 (Exhibit B)

Calculation of Requested Extension

Testing Phase (37 C.F.R. § 1.775(c) (1))

Commenced on October 30, 1994 and ended on July 15, 2002, which is 2,815 days.

Application Phase (37 C.F.R. § 1.775(c) (2))

Commenced on July 15, 2002 and ended on May 16, 2003, which is 305 days.

Regulatory Review Period (37 C.F.R. § 1.775(c))

The sum of the Testing Phase and the Application Phase is a total of **3120** days.

Reduction for Review Prior to the Issue of The Patent (37 C.F.R. §1.775 (d)(1)(i))

No reduction is applicable.

Due Diligence Reduction to Regulatory Review Period (37 C.F.R.§1.775(d)(1)(ii))

No reduction. As evidenced by Exhibit G to the original Application filed
July 14, 2003 and Exhibit J to the Supplement filed September 24, 2003,
Applicant maintains it acted with due diligence during both testing and review periods. Thus, there is no reduction in the regulatory review period because of lack of due diligence.

One-Half Testing Phase Reduction (37 C.F.R. § 1.775 (d) (1) (iii))

 $\frac{1}{2}$ (Testing Period) + Review Period = 1,713 $\frac{1}{2}$ (2815) + 305 = 1,713

Fourteen Year Cap (37 C.F.R. § 1.775 (d) (2) - (4)

In applying section 156(c) (3), the final revised regulatory review period as calculated above (1,713 days) is added onto the end of the original term of the patent, July 9, 2007, resulting in a date of March 17, 2012. Alternatively, fourteen (14) years is added to the NDA approval date (May 16, 2003) resulting in a date of May 14, 2017. The earlier of the above two dates, **March 17, 2012** is thus selected.

As shown above, the term of U.S. Patent No. 4,927,814 is eligible for an extension of 1,713 days from July 9, 2007 to March 17, 2012. Applicant confirms its request for a patent term extension, corrected to run up to and including March 17, 2012.

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